

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF TEXAS
LUBBOCK DIVISION

STATE OF TEXAS,
Plaintiff,

v.

UNITED STATES DEPARTMENT OF
HEALTH AND HUMAN SERVICES;
XAVIER BECERRA, in his official capacity
as Secretary of the United States
Department of Health and Human Services;
MELANIE FONTES RAINER, in her
official capacity as Director of the
Department of Health and Human Services
Office for Civil Rights,
Defendants.

CIVIL ACTION No. 5:24-cv-00204

**BRIEF IN SUPPORT OF TEXAS'S RESPONSE IN OPPOSITION TO DEFENDANTS' MOTION TO
DISMISS, OR IN THE ALTERNATIVE, MOTION FOR SUMMARY JUDGMENT
AND TEXAS'S MOTION FOR PARTIAL SUMMARY JUDGMENT**

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SUMMARY

Defendants' HIPAA Privacy Rule to Support Reproductive Health Care Privacy, 89 Fed. Reg. 32,976 (April 26, 2024) (2024 Rule) transforms the Health Insurance Portability and Accountability Act (HIPAA) into part of Defendants' all-of-agency response to *Dobbs v. Jackson Women's Health Org.*, 597 U.S. 215 (2022), by imposing barriers on the use and disclosure of protected health information (PHI) about "reproductive health care." While this rule is just one of Defendants' many efforts to curtail the impact and effect of *Dobbs*, see *Purl v. U.S. Dep't of Health & Hum. Servs.*, 760 F. Supp. 3d 489, 495 n.3 (N.D. Tex. 2024) (Kacsmarck, J.), the 2024 Rule has a sweeping effect on multiple State agencies and programs. It defines "reproductive health care" so broadly that it encompasses almost any care imaginable. 89 Fed. Reg. at 32,978. Not only does the 2024 Rule impede the Texas Attorney General's authority to investigate and enforce the State's prohibitions on abortion, but it also impacts everything from the State's enforcement of its laws prohibiting gender-transition experiments on children to State agencies' abilities to perform routine oversight functions required for compliance with State and federal laws.

As a court in another division within this district has already held, Congress did not authorize Defendants to use HIPAA as a roadblock to "limit" or "slow[] down" State investigations. *Purl*, 760 F. Supp. 3d at 501. On the contrary, Congress *preserved* States' enforcement authority in the statutory text: "Nothing in [HIPAA] shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth or death, public health surveillance, or public health investigation or intervention." 42 U.S.C. § 1320d-7(b). The 2024 Rule runs roughshod over this protection by restricting State officials' ability to request basic, vital information for public health

and civil enforcement actions. And it threatens criminal liability on healthcare providers who comply with State records requests by putting them in the impossible position of making legal determinations about where a State investigation may lead. This legal analysis that the 2024 Rule requires “is difficult for lawyers, much less doctors.” *Purl*, 760 F. Supp. 3d at 502.

The 2024 Rule is final agency action subject to judicial review under the Administrative Procedure Act (APA), which authorizes courts to vacate agency action that is contrary to law. 5 U.S.C. §§ 704, 706(2). Agency action is contrary to law if it exceeds the agency’s “statutory jurisdiction, authority, or limitations;” is “contrary to constitutional right, power, privilege, or immunity;” or is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A)–(C). The APA “empowers and commands courts to ‘set aside’ unlawful agency actions,” and “vacatur [will] render a challenged agency action void.” *Tex. Med. Ass’n v. U.S. Dep’t of Health & Hum. Servs.*, 110 F.4th 762, 779 (5th Cir. 2024) (cleaned up).

The Court should vacate and set aside the 2024 Rule because it is statutorily unlawful and arbitrary and capricious. 5 U.S.C. § 706(2)(A). The 2024 Rule is unlawful because it imposes limits on Texas’s authority where HIPAA allows none, and it illegally imposes requirements and restrictions on “reproductive health care” with no statutory basis. The 2024 Rule is also arbitrary and capricious: Defendants did not sufficiently consider important aspects of the problem, such as the effects of the 2024 Rule on Texas’s ability to conduct routine oversight activities in conformance with both state and federal laws.

BACKGROUND

I. Health Insurance Portability and Accountability Act (HIPAA)

HIPAA was enacted in 1996 “because health information needed more protections and the world needed more acronyms.” *Am. Hosp. Ass’n v. Becerra*, 783 F.Supp.3d 780, 788 (N.D. Tex. 2024) (Pittman, J.). “HIPAA seeks to ‘assure that individuals’ health information is properly protected’ while ‘allowing the flow of health information needed to provide and promote high quality healthcare.’” *Id.* HIPAA aims to “improve portability and continuity” and “simplify the administration of health insurance.” Pub. L. No. 104-191, 110 Stat. 1936 (1996). In enacting HIPAA, Congress balanced these objectives against the need to “address concerns about the confidentiality of patients’ individually identifiable health information.” *OPIS Mgmt. Res., LLC v. Sec’y, Fla. Agency for Health Care Admin.*, 713 F.3d 1291, 1294 (11th Cir. 2013) (citing Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, § 264, 110 Stat. 1936).

Congress accomplished these purposes through HIPAA by criminalizing a “covered entity[’s]” act of sharing a patient’s “individually identifiable health information” if done “without authorization.” 42 U.S.C. § 1320d-6. The consequence of this statutory prohibition is straightforward: “Generally, a health care provider cannot disclose [patient health] information ‘without authorization’ from the patient.” *United States v. Wilson*, 98 F.4th 1204, 1217 (10th Cir. 2024). “HIPAA provides both civil and criminal penalties for improper disclosures of medical information.” *Acara v. Banks*, 470 F.3d 569, 571 (5th Cir. 2006) (citing 42 U.S.C. §§ 1320d-5, d-6).

HIPAA authorizes disclosure of protected health information *without* patient authorization in certain circumstances, including in response to State investigations. In § 1320d-7(b), Congress explicitly preserved this authority for States in a provision entitled “Public health.” “Nothing in

[HIPAA] shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320-d7(b).

HIPAA defines “health information” broadly as encompassing “the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.” 42 U.S.C. § 1320d(4)(B). It says nothing about abortion, gender transitions, or “reproductive health care.”

II. The 2000 Rule

Since HIPAA’s enactment, HHS has promulgated regulations to implement HIPAA’s statutory provisions. *See Murphy v. Dulay*, 768 F.3d 1360, 1368 (11th Cir. 2014). One such regulation was the Privacy Rule issued in 2000, which set out “standards to protect the privacy of individually identifiable health information” covered by HIPAA, defined more specifically in the Rule as “protected health information” (PHI). *Standards for Privacy of Individually Identifiable Health Information*, 65 Fed. Reg. 82,462 (December 28, 2000) (2000 Privacy Rule); 45 C.F.R. §§ 164.501. The 2000 Privacy Rule generally applies to covered entities—“health plan[s],” “health care clearinghouse[]s,” and certain “health care provider[s] who transmit[] . . . health information in electronic form.” 45 C.F.R. § 160.102; *see id.* § 164.500.

While the 2000 Privacy Rule generally precludes using or disclosing PHI without a patient’s approval, it contains a number of exceptions, including the disclosure of PHI

- “for a law enforcement purpose to a law enforcement official,” 45 C.F.R. § 164.512(f);
- “[i]n response to an order of a court” or “a subpoena, discovery request, or other lawful process,” *id.* § 164.512(e)(1)(i), (ii);

- “to a health oversight agency for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate [health care] oversight,” *id.* 164.512(d)(1); and
- to a “public health authority . . . for the purpose of preventing or controlling disease, injury, or disability,” including “the conduct of public health surveillance, public health investigations, and public health interventions,” *id.* § 164.512(b)(1)(i).

The 2000 Privacy Rule requires that requests for PHI for these purposes meet a three-part test:

- (1) The information sought is relevant and material to a legitimate law enforcement inquiry;
- (2) The request is specific and limited in scope to the extent reasonably practicable in light of the purpose for which the information is sought; and
- (3) De-identified information could not reasonably be used.

45 C.F.R. § 164.512(f)(1)(ii)(C). HHS designed this three-part test to preserve patient privacy without “unduly compromis[ing]” States’ authorities. 65 Fed. Reg. 82,683.

Even though “HIPAA is extraordinarily expansive” and “Congress gave HHS broad authority to promulgate rules and regulations to effectuate its mandates . . . the Department’s authority isn’t absolute.” *Am. Hosp. Ass’n v. Becerra*, 738 F. Supp. 3d at 800 (citations omitted).

III. Texas Conducts Audits and Enforcement Actions to Protect Public Health

The U.S. Constitution provides the federal government only limited powers; the remainder, the “States and the people retain.” *Bond v. United States*, 572 U.S. 844, 854 (2014). Indeed, “States are not mere political subdivisions of the United States. State governments are neither regional offices nor administrative agencies of the Federal Government. The positions occupied by state officials appear nowhere on the Federal Government’s most detailed organizational chart.”

ACORN v. Edwards, 81 F.3d 1387, 1394 (5th Cir. 1996). Rather, the United States Constitution “leaves to the several States a residuary and inviolable sovereignty,” *id.* (quoting *The Federalist* No. 39, p. 245 (C. Rossiter ed. 1961)), and among the States’ reserved powers is the traditional power “to enact legislation for the public good”—i.e., the “police power.” *Id.* (citation omitted).

States have “great latitude under their police powers to legislate as to the protection of lives, limbs, health, comfort, and quiet of all persons,” *Gonzalez v. Oregon*, 546 U.S. 243, 270 (2006) (citation omitted), and it is well-established that “[t]he safety and the health of the people” are for States “to guard and protect,” *Jacobson v. Commonwealth of Mass.*, 197 U.S. 11, 38 (1905).

For example, Texas regulates the practice of medicine within its borders. *See Tex. Const. art. XVI, § 31* (“The Legislature may pass laws prescribing the qualifications of practitioners of medicine. . . .”). Indeed, “[t]here is perhaps no profession more properly open to . . . regulation” by States than the practice of medicine.” *Watson v. Maryland*, 218 U.S. 173, 176 (1910). Texas regulates both who may practice and what procedures they may perform. *See, e.g., Tex. Occ. Code § 155.001* (describing who may practice medicine in the State of Texas); *State v. Loe*, 692 S.W.3d 215, 228–29 (Tex. 2024) (“[W]e have never questioned the Legislature’s constitutional authority to regulate medical treatments—including by prohibiting certain treatments outright—for both adults and children.”).

For example, Texas’s Human Life Protection Act generally prohibits a person from knowingly performing, inducing, or attempting an abortion. *Tex. Health & Safety Code § 170A.002(a)*. The only exception to this prohibition is if the “person performing, inducing, or attempting the abortion is a licensed physician,” and, in the licensed physician’s “exercise of reasonable medical judgment,” the woman on whom the abortion is performed “has a life-

“threatening physical condition” arising from the pregnancy that places her “at risk of death or poses a serious risk of substantial impairment of a major bodily function unless the abortion is performed.” Tex. Health & Safety Code § 170A.002(b)(2). The Texas Attorney General is charged with enforcing this law and recovering civil penalties, costs, attorneys’ fees, and other civil remedies. *See id.* §§ 170A.002, 170A.005, 170A.006. As another example, the Texas Attorney General is also charged with enforcing Senate Bill 14 (S.B. 14), *id.* § 161.701–706, which prohibits a physician or health care provider from performing surgeries or prescribing testosterone, estradiol, or puberty blockers “for the purpose of transitioning a child’s biological sex . . . or affirming the child’s perception of the child’s sex if that perception is inconsistent with the child’s biological sex.” *Id.* § 161.702.

In yet another exercise of its police powers, Texas also regulates the advertisement and provision of consumer products. Texas’s Deceptive Trade Practices Act, Tex. Bus. & Comm. Code § 17.41, *et seq.* (DTPA), “provide[s] remedies for persons victimized by false, misleading and deceptive acts within the police power of the state.” *Track Trading Co. v. YRC, Inc.*, Civ. A. No. 1:22-CV-00362, 2022 WL 5027684, at *4 (W.D. Tex. Oct. 4, 2022) (quoting *Brown v. Am. Transfer & Storage*, 601 S.W.2d 931, 938 (Tex. 1980)). The Texas Office of the Attorney General (OAG) Consumer Protection Division has pursued enforcement actions against health professionals who are suspected of harming patients with unfair or deceptive business practices. For example, the Consumer Protection Division is currently involved in multiple civil enforcement actions against physicians for violations of S.B. 14.

Texas also maintains responsibility for monitoring compliance with important federal programs. For example, OAG is the “agency responsible for implementing federal Title IV-D

requirements regarding child support.” *In re Office of Atty. Gen.*, 422 S.W.3d 623, 625 n.1 (Tex. 2013). As part of its Title IV-D requirements, OAG’s Child Support Division facilitates the voluntary acknowledgment of paternity program. *See* 45 C.F.R. § 303.5 (g) (requiring States to establish a “voluntary paternity establishment program” “in cooperation with hospitals, State birth record agencies,” and other entities). Federal law stipulates that “[t]he State must assess each hospital, State birth record agency, local birth record agency designated by the State, and other entity participating in the State’s voluntary paternity establishment program . . . on at least an annual basis.” 45 C.F.R. § 303.5(g)(7). OAG’s Child Support Division “audits Texas hospitals’ compliance with the [Acknowledgment of Paternity] program” on a quarterly basis, and those audits require access to birth records. Appx.003.

Texas’s ability to effectively enforce and comply with both State and federal laws depends upon its timely access to certain medical records and health information. When covered entities deny requests for information, the State’s compliance and enforcement efforts are delayed, and it has had to seek relief through court proceedings. Appx.001–013.

IV. HHS Promulgates 2024 Rule After *Dobbs*

In June 2022, the Supreme Court “return[ed]” abortion regulation “to the people and their elected representatives” by holding that the U.S. Constitution does not require States to permit abortions. *Dobbs*, 597 U.S. at 259. Against this backdrop, on April 26, 2024, HHS published the 2024 Rule, characterizing it from the start as a response to *Dobbs*, which “enable[ed] [S]tates to significantly restrict access to abortion.” 89 Fed. Reg. 32,987. Defendants explained that the 2024 Rule is to protect PHI from being “disclosed and used to conduct [a State] investigation against, or to impose liability upon” a person after *Dobbs* removed the “constitutional right to abortion.” *Id.*

at 32,978. In promulgating the rule, HHS cited *Zurawski v. State of Texas*, a 2023 case which challenged Texas's abortion regulations in the wake of *Dobbs*. 89 Fed. Reg. 33,058. And on announcing the 2024 Rule, Secretary Becerra stated, "We're making it clear: you have the right to privacy—*Dobbs* did not take it away."¹ The 2024 Rule creates new restrictions on disclosure of PHI by creating a new category of health care—"reproductive health care"—and crafting special rules for that category. 45 C.F.R. § 160.103. The definition of "reproductive health care" encompasses the "full range of health care related to an individual's reproductive health," *id.* at 33,005, including "all matters relating to the reproductive system and to its functions and processes," *id.* at 33,063. The definition of "reproductive health care" includes medical services associated with "gender identity." 89 Fed. Reg. at 32,989 n.163. As a result, the 2024 Rule's requirements apply not only to abortions but also to so-called gender transitions.

The 2024 Rule imposes barriers on using and disclosing this new category of health care, even though Defendants acknowledge that those barriers "may affect certain state interests in obtaining PHI to investigate potentially unlawful" conduct. *Id.* at 32,995. The 2024 Rule prohibits the disclosure of information about "reproductive health care" for at least three specific purposes:

- (1) [t]o conduct a criminal, civil, or administrative investigation into any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[;]
- (2) [t]o impose criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating reproductive health care[; or]
- (3) [t]o identify any person [for these purposes].

¹ Secretary Xavier Becerra (@SecBecerra), X (Apr. 22, 2024, 11:32 PM), <https://x.com/SecBecerra/status/1782432173665960400>. Appx.567.

45 C.F.R. § 164.502(a)(5)(iii)(A).

The 2024 Rule's disclosure bar applies only if State or federal law deems the medical service "lawful" under the circumstances it was provided. It states that the bar applies only if the covered entity "reasonably determine[s] that one or more of the following conditions exists":

- (1) [t]he reproductive health care is lawful under the law of the state in which such health care is provided under the circumstances in which it is provided[;]
- (2) [t]he reproductive health care is protected, required, or authorized by Federal law, including the United States Constitution, under the circumstances in which such health care is provided, regardless of the state in which it was provided[; or]
- (3) [t]he presumption [that the "reproductive health care" at issue was lawful] applies.

Id. § 164.502(a)(5)(iii)(B). By these terms, the covered entity itself determines if the "reproductive health care" it furnished was lawful—and not the State officials tasked with enforcing the laws.

As indicated above, the 2024 Rule creates a "presumption" that "reproductive health care" provided by another person is lawful. *See id.* § 164.502(a)(5)(iii)(B)(3) & (C). The presumption is overcome only if (1) the covered entity has actual knowledge that the reproductive health care was *not* lawful, or (2) the person requesting disclosure of PHI supplies "[f]actual information . . . that demonstrates a substantial factual basis that the reproductive health care was not lawful." *Id.* § 164.502(a)(5)(iii)(C). In declining to disclose PHI in response to a government request, a covered entity can cite the 2024 Rule to support the proposition that it has "reasonably determined" that the reproductive health care was lawful. 45 C.F.R. § 164.502(a)(5)(iii)(B). The 2024 Rule leaves the complex determination whether the information is sought for a prohibited purpose up to the covered entity—including when that entity is the one under investigation. Defendants go so far as

to say that covered entities determine whether reproductive health care is “lawful” because “the interests of law enforcement . . . are outweighed by privacy interests[.]” 89 Fed. Reg. 33,014.

The 2024 Rule also adds an attestation requirement. 45 C.F.R. § 164.509. Under this provision, a covered entity or business association may not use or disclose PHI “potentially related to reproductive health care” for any purpose, including to comply with a State law enforcement investigation, without obtaining an attestation that is valid. 45 C.F.R. § 164.509(a). This requires public officials requesting PHI to swear the request is not being made for purposes prohibited by the 2024 Rule. 45 C.F.R. § 164.509(a)(1); *see id.* § 164.512. “The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, non-required statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed.” *Purl*, 760 F. Supp. 3d at 503. The 2024 Rule prohibits disclosure if the attestation is deficient. If HHS subsequently determines that the attestation is deficient, the covered entity incurs liability. *See* 45 C.F.R. § 164.509(a)(2). The 2024 Rule even threatens State officials with federal criminal charges should they send a noncomplying attestation or if HHS deems the attestation to have been submitted “for a purpose prohibited” by the 2024 Rule. *Id.* § 164.509(c)(1)(iv) & (v).

Crafted to stymy State enforcement actions for violations of their laws on abortion and so-called gender transitions, the 2024 Rule excludes from its definition of “public health” those “services.” In doing so, Defendants attempt to remove those subjects from Congress’s instruction that HIPAA cannot place “limit[s]” on “public health surveillance,” “public health investigation,”

and “public health intervention.” 89 Fed. Reg. at 33,062–63 (codified at 45 C.F.R. § 160.103); *see* 42 U.S.C. § 1320d-7(b).

Finally, the 2024 Rule allows disclosure of “reproductive health care” information when it is used or disclosed by a covered entity “for the purpose of defending themselves or others against allegations that they sought, obtained, provided, or facilitated reproductive health care.” 89 Fed. Reg. 33,011 (codified at 45 C.F.R. § 164.502(a)(5)(iii)(D)). So a covered entity who has performed abortions or “gender-transition” procedures may disclose the same “reproductive health care” information that the 2024 Rule would prohibit State officials from receiving.

SUMMARY JUDGMENT STANDARD

“In the context of a challenge to an agency action under the APA, ‘[s]ummary judgment is the proper mechanism for deciding, as a matter of law, whether an agency action is supported by the administrative record and consistent with the APA standard of review.’” *Texas v. United States Dep’t of Transportation*, 726 F. Supp. 3d 695, 707 (N.D. Tex. 2024) (Hendrix, J.) (citing *Blue Ocean Inst. v. Gutierrez*, 585 F. Supp. 2d 36, 41 (D.D.C. 2008)). “When assessing a summary judgment motion in an APA case, ‘the district judge sits as an appellate tribunal’ and ‘[t]he entire case on review is a question of law, and only a question of law.’” *Permian Basin Petroleum Ass’n v. Dep’t of the Interior*, 127 F. Supp. 3d 700, 706 (W.D. Tex. 2015) (citing *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083 (D.C. Cir. 2001); *Marshall Cnty. Health Care Auth. v. Shalala*, 988 F.2d 1221, 1226 (D.C. Cir. 1993)). “Indeed, ‘[i]t is well established that when a district court reviews a summary judgment motion concerning an agency’s action, the court determines not whether the material facts are disputed, but whether the agency properly dealt with the facts.’” *Texas v. U.S. Dep’t of Health & Human Servs.*, Civ. A. No. 23-CV-00022, 2024 WL 1493809, at *3 (W.D. Tex. Apr. 5,

2024) (Counts, J.) (quoting *Garcia for Congress v. Fed. Elec. Comm'n*, 22 F. Supp. 3d 655, 659 (N.D. Tex. 2014)). If the agency exceeded its statutory authority or acted arbitrarily or capriciously, the court must “hold unlawful and set aside” the challenged action. 5 U.S.C. § 706(2)(A), (C).

ARGUMENT

As a court in another division within this district has recognized, the 2024 Rule imposes limitations on the disclosure of PHI that Congress explicitly prohibited. *Purl*, 760 F. Supp. 3d at 501. Whether Defendants exceeded their statutory authority in promulgating the 2024 Rule and whether they acted arbitrarily and capriciously in doing so can be resolved on the administrative record without further factual development. *See, e.g., PayPal, Inc. v. CFPB*, 728 F. Supp. 3d 31, 38 (D.D.C. 2024).

I. Texas has standing.

Defendants claim Texas lacks standing, contending that “Texas is not itself the object of the government action it challenges,” *see* Dkt. 20 at 16–17 (internal quotations omitted), but this argument fails.

To establish standing, “[t]he plaintiff must have (1) suffered an injury in fact, (2) that is fairly traceable to the challenged conduct of the defendant, and (3) that is likely to be redressed by a favorable judicial decision.” *Spokeo, Inc. v. Robins*, 578 U.S. 330, 228 (2016) (quoting *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992)). Texas is a sovereign State with an interest in “the exercise of sovereign power over individuals and entities within the relevant jurisdiction” which “involves the power to create and enforce a legal code, both civil and criminal.” *Alfred L. Snapp & Son, Inc. v. Puerto Rico, ex rel., Barez*, 458 U.S. 592, 601 (1982); *Tex. Off. of Pub. Util. Couns. v. FCC*, 183 F.3d 393, 449 (5th Cir. 1999). Therefore, Texas “may have standing based on (1) federal

assertions of authority to regulate matters [it] believe[s] [it] control[s], (2) federal preemption of state law, and (3) federal interference with the enforcement of state law.” *Texas v. United States (DAPA)*, 809 F.3d 134, 153 (5th Cir. 2015) (cleaned up and citations omitted), *aff’d by an equally divided court sub nom. United States v. Texas*, 136 S. Ct. 2271, 2272 (2016).

The 2024 Rule directly regulates Texas. Texas operates HIPAA-covered entities that are now required to execute attestations. Appx.001–013. Texas also investigates public health violations, the performance of which now also includes the obligation to make attestations. Appx. 052–379; 415–565. In addition to this regulatory burden, the 2024 Rule forces Texas to incur compliance obligations—which require time, resources, and personnel—and slows investigations intended to promote Texas’s sovereign interest in safeguarding its citizens’ “health, comfort, and welfare.” *Kentucky v. Biden*, 23 F.4th 585, 596 (6th Cir. 2022); *see also Texas v. Becerra*, 577 F. Supp. 3d 527, 558–559 (N.D. Tex. 2021) (Hendrix, J.) (finding that Texas had *parens patriae* standing when it asserted an interest “in the health and well-being” of its residents (quoting *Alfred L. Snapp & Son, Inc.*, 458 U.S. at 607)).

The 2024 Rule is unlawful because it obstructs the Texas’s ability to enforce its own laws on abortion and other laws that Defendants contend fall under the umbrella of “reproductive health care,”—to include any “health care . . . that affects the health of an individual in all matters relating to the reproductive system and to its functions and processing.” 45 C.F.R. § 160.103. Numerous courts have made clear that preventing the State from enforcing its laws constitutes irreparable harm. *See, e.g., Abbott v. Perez*, 138 S. Ct. 2305, 2324 n.17 (2018) (“[T]he inability to enforce its duly enacted plan clearly inflicts irreparable harms on the State.”); *Maryland v. King*, 567 U.S. 1301, 1303 (2012) (“Any time [a State is blocked] from effectuating statutes enacted by representatives

of its people, it suffers a form of irreparable injury.”). Indeed, in support of the rule’s terms, Defendants rely on plaintiffs’ petition in *Zurawski v. State of Texas*, No. D-1-GN-23-000968, Travis County, Texas—a case brought by several plaintiffs against the Texas Attorney General and the Texas Medical Board challenging Texas’s abortion laws. *See* 89 Fed. Reg. 33,058 n.446, n. 447; *State v. Zurawski*, 690 S.W.3d 644, 654 (Tex. 2024).

The 2024 Rule is an obstacle to Texas’s ability to conduct everything from routine audits to enforcement actions related to public health and safety. Appx.001–013; 052–379; 415–565. While Defendants contend that “the 2024 Rule does not prevent a [S]tate from obtaining information related to the provision of unlawful reproductive health care,” Dkt. 20 at 9, it is doing exactly that.

For example, the 2024 Rule is impeding two ongoing OAG enforcement actions seeking to enjoin violations of S.B. 14. Appx.052–565. In October 2024, Texas filed suit against Dr. May Lau for “prescribing testosterone, a controlled substance, to biological female minors for the purposes of transitioning their biological sex or affirming their belief that their gender identity is inconsistent with their biological sex” in violation of S.B. 14. Appx.016, *State of Texas v. May C. Lau, M.D.*, Cause No. 493-07676-2024, 493rd District Court, Collin County, Texas, filed Oct. 17, 2024. Subsequently, OAG attorneys issued subpoenas to several third parties, including Children’s Health, ESI Mail Pharmacy Service, CVS Pharmacy, H-E-B Pharmacy, and Walgreens Pharmacy, seeking the production of documents and communications relevant to the case. Appx.052–379. Even though the court had issued a protective order stipulating that “the attestation provision is not applicable in this cause, including but not limited for the reason the information is not sought for a prohibited purpose,” Appx.188, these entities still refused to comply with the subpoena in the absence of the attestation required by 45 C.F.R. § 164.509. Appx.055; 099–100; 160, 167; 234, 241;

308, 315. Several nonparty patients whose information was requested from CVS, H-E-B, and Walgreens proceeded to file lawsuits of their own against Texas in three separate jurisdictions, requesting protective orders “includ[ing] a requirement that the State provide an attestation that conforms to [the 2024 Rule].” Appx.167, *Nonparty Patient Nos. 1 and 2 v. State of Texas*, Cause No. DC-25-07810, 95th District Court, Dallas County, Texas, filed May 19, 2025; Appx.241, *Nonparty Patient No. 1 v. State of Texas*, Cause No. 2025CI11287, 285th District Court, Bexar County, Texas, filed May 19, 2025; Appx.315, *Nonparty Patients Nos. 1–6 v. State of Texas*, Cause No. D-1-GN-25-003645, 250th District Court, Travis County, Texas, filed May 19, 2025. Children’s Health and ESI Mail Pharmacy Service also filed motions for protective orders, citing the 2024 Rule. Appx.055; 097, 099–100.

In November 2024, Texas filed a similar enforcement action against Dr. M. Brett Cooper for violations of S.B. 14. Appx.380, *State of Texas v. M. Brett Cooper, M.D.*, Cause No. 493-08026-2024, 493rd District Court, Collin County, Texas, filed Nov. 4, 2024. Just as the *Lau* court had done, the *Cooper* court issued a protective order which provided that the attestation required by 45 C.F.R. § 164.509 did not apply, Appx.445; yet just as before, when OAG attorneys sent subpoenas to third parties seeking relevant documents and communications, the third parties responded by filing suits of their own, citing the 2024 Privacy Rule and requiring an attestation as a condition of complying with the subpoena. Appx.417, 424, *Nonparty Patients Nos. 1–6 v. State of Texas*, Cause No. DC-25-07984, 193rd District Court, Dallas County, Texas, filed May 19, 2025; Appx.490, 497 *Nonparty Patients Nos. 1–5 v. State of Texas*, Cause No. D-1-GN-25-003646, 261st District Court, Travis County, Texas, filed May 19, 2025; *see also* Appx.561–65 (Kroger Pharmacy refusing to release information without an attestation despite the court’s protective order). These two

enforcement actions against Dr. Lau and Dr. Cooper have now generated at least five additional lawsuits in which Texas must prevail before obtaining information necessary to prosecute violations of S.B. 14. Appx.158–378, 415–559. The attestation requirement is hampering Texas’s enforcement of its own laws and requiring it to dedicate personnel time and resources to vindicate the State’s sovereign interests.

The attestation requirement has also begun to impede the functions of the Child Support Division of OAG. Appx.002–003. The Child Support Division is charged with fulfilling “federally-mandated responsibilities” to administer “the voluntary acknowledgement of paternity (AOP) program.” Appx.002 at ¶ 3. Part of those “federally-mandated responsibilities” involve conducting audits of Texas hospitals to ensure they are in compliance with the AOP program, which require the Child Support Division to request “patient health information without authorization from the parent.” Appx.003 at ¶ 5. The attestation requirement has generated additional delays and compliance costs to this process, which “ran smoothly, with hospitals providing necessary information to OAG staff upon request” until the implementation of the 2024 Rule. *Id.*

Similarly, the attestation requirement is interfering with the Texas Department of State Health Services’ (DSHS) ability to obtain information necessary to review pregnancy-related deaths. Appx.006 at ¶ 3. State law requires hospitals and other custodians of relevant records to provide information to DSHS for review by the Maternal Mortality and Morbidity Review Committee. *Id.* (citing Tex. Health & Safety Code § 34.008(b)(2)). Indeed, Defendants cite the Texas Maternal Mortality and Morbidity Review Committee and DSHS Joint Biennial Report to support the proposition that the 2024 Rule “will likely contribute to a decreased rate of maternal mortality and morbidity by improving access to information about health services.” 89 Fed. Reg.

33,058 n. 445. But since the 2024 Rule went into effect, DSHS has received requests for attestations, and its “study and review of specific cases has been delayed while DSHS seeks legal counsel on the implications of signing the attestations.” *Id.* at ¶ 4. Likewise, since the 2024 Rule took effect, DSHS has received requests to execute attestation forms from covered entities in response to requests for medical records that relate to the occurrence of a birth defect. *Id.* at ¶ 5. While State law requires health facilities and health professionals to make those records available to DSHS, the agency is encountering pushback based on the 2024 Rule. *See id.*

The 2024 Rule imposes regulatory burdens on Texas, and “[a]n increased regulatory burden typically satisfies the injury in fact requirement.” *Texas v. EEOC*, 933 F.3d 433, 446 (5th Cir. 2019) (quoting *Contender Farms, L.L.P. v. U.S. Dep’t of Agric.*, 779 F.3d 258, 266 (5th Cir. 2015)). Indeed, “regulations that require or forbid some action by the plaintiff almost invariably satisfy both the injury in fact and causation requirements.” *FDA v. All. for Hippocratic Med.*, 602 U.S. 367, 382 (2024). For example, Texas agencies have incurred—and will continue to incur—compliance costs. Appx.001–010. Indeed, Defendants expect and acknowledge that covered entities will incur compliance costs, including costs associated with attestations. *See* 89 Fed. Reg. 33,056–57. Altogether, Texas’s sovereign and fiscal injuries constitute “specific summary judgment evidence showing that [Texas] was directly affected” by the challenged agency action. *Texas State LULAC v. Elfant*, 52 F.4th 248, 255 (5th Cir. 2022) (quoting *ACORN v. Fowler*, 178 F.3d 350, 354 (5th Cir. 1999)).

II. The 2024 Rule is contrary to statute and exceeds the authority granted by Congress.

“A federal agency cannot act without Congressional authorization. . . . It cannot confer power upon itself.” *Texas v. Becerra*, 667 F. Supp. 3d 252, 269 (N.D. Tex. 2023) (Hendrix, J.) (citing

La. Pub. Serv. Comm'n v. FCC, 476 U.S. 355, 374 (1986)), *vacated in part*, No. 23-10564, 2024 WL 2747751 (5th Cir. Feb. 2, 2024)). “The ‘core inquiry’ in an APA case is whether the rule in question is a ‘lawful extension of the statute under which the agency purports to act, or whether the agency has indeed exceeded its ‘statutory jurisdiction, authority, or limitations.’” *Texas v. United States Dep’t of Transportation*, 726 F. Supp. 3d 695, 708 (N.D. Tex. 2024) (Hendrix, J.) (citing *VanDerStok v. Garland*, 86 F.4th 179, 187–88 (5th Cir. 2023)). To determine whether HHS “has stayed within the bounds of its statutory authority,” *City of Arlington v. FCC*, 569 U.S. 290, 297 (2013), courts begin with the statute’s text to “determine[e] the meaning of statutory provisions.” *Loper Bright Enters. v Raimondo*, 603 U.S. 369, 394 (2024). “Sometimes, statutes grant agencies discretion to interpret and other times, they do not. . . . When they do not, courts exercise their role and Congress’s mandate to interpret the statute free from an agency’s read.” *Purl*, 760 F. Supp. 3d at 500 (citing *Loper Bright*, 603 U.S. at 394).

Recognizing States’ traditional police powers over public health and welfare, Congress explicitly mandated that “[n]othing in [HIPAA] shall be construed to invalidate or *limit* the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d-7(b) (emphasis added). Accordingly, whether the 2024 Rule “exceeds statutory authority turns on the meaning of ‘limit’ in HIPAA.” *Purl*, 760 F. Supp. 3d at 500. HHS is not entitled to deference on what “limit[s]” are allowed. Instead, this Court’s interpretation of the statute’s “single, best meaning” must control. *Loper Bright*, 603 U.S. at 371, 400.

Because HIPAA does not define “limit,” it must be given its “ordinary, common meaning as understood by the people it governs.” *Purl*, 760 F. Supp. 3d at 501 (collecting cases). A “limit” is a “restriction or restraint.” *Limits*, Black’s Law Dictionary (12th ed. 2024). “All agree that something is *limited* when restrictions, restraints or curtailments are imposed.” *Purl*, 760 F. Supp. 3d at 501. “[L]aws that curtail or restrain the activity—even if the activity is not completely prohibited—*limit* the activity through imposing obstructions to the relevant activity.” *Id.*

The 2024 Rule “impos[es] obstructions” to Texas’s “authority, power, or procedures . . . for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention” by placing obstacles to its exercise over these matters of public concern. *See Purl*, 760 F. Supp. 3d at 500.

HHS may not impose requirements that not only go beyond the text of the authorizing statute but actually contradict it. Congress went out of its way to preserve State investigative authority when it passed HIPAA. The statutory language is clear: “Nothing in this part [unauthorized disclosures] shall be construed to *invalidate or limit* the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d-7(b) (emphasis added). Courts have long recognized that HIPAA’s protection of PHI is constrained by this and similar anti-preemption provisions. *Wassef v. Tibben*, 68 F.4th 1083, 1089 (8th Cir. 2023); *see also Seaton v. Mayberg*, 610 F.3d 530, 541 (9th Cir. 2010) (noting that Congress “evidently recogniz[ed] the well-established need for disclosure” in situations excepted from HIPAA’s preemption provision); *Citizens for Health v. Leavitt*, 428 F.3d 167, 172 (3d Cir. 2005). Moreover, nothing in HIPAA authorizes Defendants to construe the statute’s bar on disclosure

“without authorization” to include disclosures to a State government that are provided pursuant to compulsory process, such as a subpoena. 42 U.S.C. § 1320d-6(a)(3).

Yet, when Defendants promulgated the 2024 Rule, they defied Congress’s express directive that HHS may not limit these types of disclosures necessary for public health investigations, and instead imposed sharp limits on the State’s investigative authority into “reproductive health care.”

For example, the 2024 Rule requires covered entities to screen all PHI before disclosure “for whether it contain[s] information potentially related to reproductive health care,” 89 Fed. Reg. at 33,060, and “determine whether the relevant ‘reproductive health care’ was ‘lawful’ under the circumstances it was acquired.” *Purl*, 760 F. Supp. 3d at 502. That process is significant. The 2024 Rule’s definition of “reproductive health care” is intentionally broad, requiring an extensive screening process because almost any patient record could be “potentially related” to the “functions and processes” of the reproductive system. 45 C.F.R. § 160.103.

Once a covered entity determines that “reproductive health care” information is implicated, the 2024 Rule triggers a second inquiry: Whether the requesting State or local agency is “conduct[ing] a criminal, civil, or administrative investigation into or to impos[ing] criminal, civil, or administrative liability on any person for the mere act of seeking, obtaining, providing, or facilitating lawful reproductive health care.” 89 Fed. Reg. 32,989–32,990. In effect, the party receiving the inquiry is tasked with evaluating the investigators’ motive. And in any event, at the investigation stage, State officials do not yet know whether health information will reveal unlawful conduct. The purpose of collecting the information is to determine whether unlawful conduct has occurred. In the circumstance in which the covered entity is itself the target of an investigation,

this requirement allows the entity to sidestep enforcement actions and strip the State of its investigative authority.

This inquiry is made even more problematic by the fact that the 2024 Rule’s disclosure prohibition applies only if the medical service is “lawful” under the circumstances in which it was provided. 89 Fed. Reg. at 33,063. This limitation is particularly acute as it applies to abortion. For example, HHS previously maintained to this Court that federal law required performance of abortions even in situations where it would be prohibited by Texas law. *Texas v. Becerra*, 623 F. Supp. 3d 696, 710, 712 (N.D. Tex. 2022) (Hendrix, J.). And HHS maintains guidance that there are “abortions that are ‘lawful’ under federal law” that may otherwise be prohibited by State law. *See Guidance on Nondiscrimination Protections Under the Church Amendment*, Dep’t of Health & Hum. Servs. (Feb. 3, 2023), <https://www.hhs.gov/conscience/conscience-protections/guidance-church-amendments-protections/index.html> (<https://perma.cc/59C4-FJE8>) (stating that “it is unconstitutional for a state to prohibit a patient from ending a pregnancy prior to fetal viability”). This provision of the 2024 Rule would allow a physician to make a legal determination that an abortion he performed was “lawful” and thereby refuse to provide information to State investigators.

Even if a physician *weren’t* trying to avoid complying with a request for information from a State official, the 2024 Rule requires doctors “to navigate whether an abortion was ‘legal’ under EMTALA, and therefore federal law, before disclosing and risking liability under HIPAA. Such questions confounded Article III courts—never mind medical professionals.” *Purl*, 760 F. Supp. 3d at 502. Defendants acknowledge that law enforcement and covered entities may disagree on whether reproductive health care was lawful, and, in that circumstance, disclosure is *prohibited*:

The Department recognizes that situations may arise where a regulated entity reasonably determines that reproductive health care was lawfully provided, while at the same time, the person requesting the PHI (*e.g.*, law enforcement) reasonably believes otherwise. In such circumstances, where the regulated entity . . . reasonably determines that the provision of reproductive health care was lawful, the final rule would prohibit the regulated entity from disclosing PHI.

89 Fed. Reg. 32,993.

The attestation requirement imposes yet another impermissible “limit.” *Purl*, 60 F. Supp. 3d at 503. Under it, “[a] covered entity . . . may not use or disclose protected health information potentially related to reproductive health care for purposes specified in [the 2024 Rule] without obtaining an attestation[.]” 89 Fed. Reg. at 33,063. There are strict requirements for what constitutes a valid attestation: “The requesting agency must say the information will not be used for a prohibited purpose; must not contain any extra, nonrequired statements; must be believable to a reasonable covered entity; must contain a specific description of the sought information; must contain a statement that a covered entity could be subject to penalties for a HIPAA violation; must be in plain language; and must be signed.” *Purl*, 760 F. Supp. 3d at 503. This attestation requirement cripples investigations, because it forecloses investigators’ ability to use the information to “conduct a criminal, civil, or administrative investigation” into the provision of “reproductive health care,” regardless of what the information may show. 45 C.F.R. § 164.509(a); *id.* § 164.502(a)(5)(iii)(1). Even in the context of a court ordered warrant, a covered entity may still refuse to produce records:

For example, a regulated entity receives an attestation from a Federal law enforcement official, along with a court ordered warrant demanding PHI potentially related to reproductive health care. The law enforcement official represents that the request is about reproductive health care that was not lawful under the

circumstances in which such health care was provided, but the official will not divulge more information because they allege that doing so would jeopardize an ongoing criminal investigation. In this example, if the regulated entity itself provided the reproductive health care and, based on the information in its possession, reasonably determines that such health care was lawful under the circumstances in which it was provided, the regulated entity may not disclose the requested PHI.

Id. at 33,032.

The 2024 Rule also adds a presumption that reproductive health care provided by another person was lawful unless the covered entity has “[a]ctual knowledge that the reproductive health care was not lawful” or “[f]actual information supplied by the person requesting the use or disclosure of protected health information that demonstrates a substantial factual basis that the reproductive health care was not lawful.” 89 Fed. Reg. 33,063 (change codified at 45 C.F.R. § 164.502(a)(5)(iii)(C)). This presumption against disclosure requires State officials to divulge specific facts about an investigation sufficient to establish a “substantial factual basis” about what they expect the investigation may reveal. This intrudes on the State’s ability to conduct investigations when the purpose of the records requests is to gather facts to determine whether unlawful acts occurred.

The 2024 Rule is further contrary to law because its definition of “public health” unlawfully narrows the State’s ability to investigate and prosecute violations of the State’s laws governing abortions and “gender-transition” procedures on minors, because it excludes them from reporting requirements protected from limitation by 42 U.S.C. § 1320d-7(b). This violates HIPAA’s anti-preemption provision, under which HHS cannot limit “any” State public health reporting procedures. 42 U.S.C. § 1320-7(b).

In support of the 2024 Rule’s “heightened protections” for “reproductive health care” information, Dkt. 20 at 27, Defendants rely on regulations governing disclosure of psychotherapy notes. *See id.* at 28. But the regulations governing the disclosure of psychotherapy notes, 45 C.F.R. § 164.508(a)(2)(ii), explicitly allow disclosure “for oversight activities authorized by law, including audits; civil, administrative, or criminal investigations; inspections; licensure or disciplinary actions; civil, administrative, or criminal proceedings or actions; or other activities necessary for appropriate oversight,” 45 C.F.R. § 164.512(d), unabridged by the 2024 Rule’s “prohibited purposes.” And in any event, the regulations Defendants cite govern a type of record—“psychotherapy *notes*,” not a type of health care or health condition. *See* Dkt. 20 at 28 (citing 45 C.F.R. § 164.508). Abortions, so-called gender transitions, and “reproductive health care” are not records—they are, as this rule considers them, a type of “health care.”

These “impediments, restraints, or curtailments to eventual disclosure” are impermissible hurdles to the State’s exercise of authority over “procedures . . . for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.” 42 U.S.C. § 1320d-7(b). Congress made clear that “[n]othing” in HIPAA shall impose limits on States’ authority with respect to policing public health and welfare. 42 U.S.C. § 1320d-7(b). Defendants’ reliance on HHS’s general authority to issue regulations governing the use and disclosure of PHI, Dkt. 20 at 29, is unavailing. Congress specifically mandated that HHS’s authority could not be wielded to override States’ authorities. *See* 42 U.S.C. § 1320d-7(b). Accordingly, the 2024 Rule exceeds HHS’s statutory authority and should be “set aside.” 5 U.S.C. § 706(2)(C).

Even if Congress meant to impose the conditions of the 2024 Rule through HIPAA, it would violate the Major Questions Doctrine’s requirement of a clear statement. “Defendants rely as authority to enact the 2024 Rule the general organizing statutes for the agency, Dkt. 20 at 27 (citing 42 U.S.C. § 1320d-2), but such “broad grants of authority . . . cannot reasonably be construed as assigning decisions of vast economic and political significance,” such as the 2024 Rule’s special regime for “reproductive health care,” “to an agency.” *DAPA*, 809 F.3d at 183. Agencies only have those powers given to them by Congress, and enabling legislation is generally not an open book to which an agency may add pages and change the plot line.” *West Virginia v. EPA*, 597 U.S. 697, 722–23 (2022).

Here, HHS admits that the 2024 Rule was a direct response to the Supreme Court’s decision to return abortion regulation to the States, 89 Fed. Reg. at 32,987–88. As the Supreme Court described, “Americans continue to hold passionate and widely divergent views on abortion, and state legislatures have acted accordingly.” *Dobbs*, 597 U.S. at 230. Had Congress intended to authorize HHS to regulate “reproductive health care” information differently than other forms of patient information under HIPAA, it needed to do so “clearly.” *West Virginia v. EPA*, 597 U.S. at 716, 721. Defendants contend that the 2024 Rule’s requirements “do not involve a controversy of great economic and political significance.” Dkt. 20 at 28. But HIPAA’s requirements apply to nearly all healthcare providers across the country, *see* 45 C.F.R. § 160.103, and the 2024 Rule implicates some of the most hotly debated issues—regulation of abortion and so-called gender-transition procedures for minors. Defendants do not point to any language—let alone clear text—conferring it with power to create heightened disclosure regimes for “reproductive health care” information. *See* Dkt. 20 at 28–29.

III. The 2024 Rule is arbitrary and capricious.

The 2024 Rule should also be set aside under the APA as arbitrary and capricious agency action. The APA requires that agency action be “reasonable and reasonably explained.” *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021)). Agency action is arbitrary and capricious if the agency failed “to engage in ‘reasoned decisionmaking’” in taking the action. *Dep’t of Homeland Sec. v. Regents of the Univ. of Cal.*, 591 U.S. 1, 16 (2020) (quoting *Michigan v. EPA*, 576 U.S. 743, 750 (2015)). In particular, agency actions are arbitrary and capricious when they fail to consider the reliance interests of parties subject to previous norms or fail to consider alternative approaches. *Id.* at 26–33. “When an agency changes course . . . it must be cognizant that longstanding policies may have engendered serious reliance interests that must be taken into account” and “[i]t would be arbitrary and capricious to ignore such matters.” *Id.* at 30.

The 2024 Rule imposes new and significant obstacles to Texas’s ability to investigate violations of State law. The 2024 Rule does not reflect that the agency considered an “important aspect of the problem”—namely, how the 2024 Rule would impact States’ ability to conduct audits of covered entities related to their participation in federal programs. *Dep’t of Comm. v. New York*, 588 U.S. 752, 802 (2019) (Breyer, J., concurring in part, dissenting in part) (cleaned up).

For example, in conformance with 45 C.F.R. § 303.5(g)(7), the OAG’s Child Support Division conducts audits of Texas hospitals’ compliance with the voluntary acknowledgement of paternity program. Appx.002–003. “[T]his process ran smoothly, with hospitals providing necessary information to OAG staff upon request” until the 2024 Rule went into effect. Appx.003 at ¶ 5. Similarly, Texas Health and Human Services Commission Office of Inspector General performs oversight functions related to the Texas Medicaid program, including hospital utilization

reviews, as required by Title 42, Part 456 of the Code of Federal Regulations. Appx.009 at ¶ 1. In response to a request for records, a covered entity refused to disclose information without an attestation. Appx.009–013. Likewise, although HHS considered information highlighting the importance of vital statistics, including mortality surveillance, Dkt. 49-3 at 105, since the 2024 Rule went into effect, Texas’s Maternal Mortality and Morbidity Review Committee’s “study and review of specific cases has been delayed while DSHS seeks legal counsel on the implications” of signing the attestations that covered entities now demand. Appx.006 at ¶ 4. The administrative record includes a statement from the CDC: “Our federal data assets are only as strong as our state and local resources.” Dkt. 49-3 at 106. The agency failed to consider the impact and compliance costs of the 2024 Rule on State authorities tasked with collecting surveillance data.

Instead of giving these considerations the weight they were due, HHS dismissed them, choosing instead to focus wholly on their objective: curtailing States’ ability to enforce their abortion laws. In promulgating the 2024 Rule, HHS relied on a guidance document it issued days after *Dobbs* was decided: “[a]ccess to comprehensive reproductive health care services, including abortion care, is essential to individual health and well-being.” Dkt. 24-2 at 619 (citing “Guidance on the HIPAA Privacy Rule and Disclosures of Information Relating to Reproductive Health Care” in the context of “Post *Dobbs*”). In the guidance document, HHS opined that “[a]ccess to comprehensive reproductive health care services, including abortion care, is essential to individual health and well-being” and claimed that “[the 2000 HIPAA Privacy Rule] supports such access” to abortion. *Id.* Contorting the objective of the 2000 Rule to render State law unenforceable in an effort to advance a political agenda can hardly be described as reasoned decisionmaking.

Defendants' explanatory failures do not end there. The 2024 Rule requires covered entities who receive requests for PHI to determine the legality of the "reproductive health care" involved in the request. 89 Fed. Reg. 33,063. But "many covered entities are not prepared or equipped to make nuanced legal judgments." *Purl*, 760 F. Supp. 3d at 502. It is not reasonable to require covered entities to independently make complex legal judgments outside their usual purview before they may comply with Texas's requests for necessary information.

Nor is it reasonable to require covered entities to presume that "reproductive health care" is lawful without "factual information" to the contrary. 45 C.F.R. § 164.502(a)(5)(iii)(C). This presumption requires health care providers to ignore what they may know about the law—*e.g.*, that Texas generally prohibits the performance of abortions and gender-transition procedures on minors. *See Tex. Health & Safety Code* § 170A.002; *id.* § 161.702. The 2024 Rule is neither reasonable, nor reasonably explained, in forcing HIPAA-covered entities to presume such procedures are legal.

To make matters worse, Defendants consider a procedure legal any time "[t]he reproductive health care is protected, required, or authorized by Federal law . . . , regardless of the state in which it is provided." 45 C.F.R. § 164.502(a)(5)(iii)(B)(2). The 2024 Rule requires covered entities to engage in a complex legal analysis to determine whether reproductive health care—even if illegal under State law—was nonetheless "authorized by federal law."

Defendants "entirely failed to consider [these] important aspect[s] of the problem." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). The resulting regulatory scheme does not satisfy the APA's requirements and is arbitrary and capricious.

IV. The scope of requested relief is proper.

The APA instructs that courts “shall . . . hold unlawful and set aside” any agency action that is “arbitrary, capricious,” or “in excess of statutory jurisdiction [or] authority.” 5 U.S.C. § 706(a)(A), (C). This provision authorizes vacatur of unlawful final agency action. *Data Marketing Partnership, LP v. U.S. Dep’t of Labor*, 45 F.4th 846, 859 (5th Cir. 2022) (“The default rule is that vacatur is the appropriate remedy.”); *see also Kentucky v. EPA*, 123 F.4th at 472–73; *Corner Post, Inc. v. Bd. of Governors of Fed. Reserve Sys.*, 603 U.S. 799, 829 (2024) (Kavanaugh, J., concurring) (“[T]he APA authorizes vacatur of unlawful agency actions, including agency rules.”).

Defendants contend the APA “does not *require* courts to vacate federal rules,” Dkt. 20 at 34, and cite *Texas v. Biden*, 20 F.4th 928 (5th Cir. 2021) for the proposition that vacatur “depends on ‘the seriousness of the deficiencies of the action’ and ‘the disruptive consequences of vacatur.’” Dkt. 20 at 34–35. But Defendants ignore that, in that case, the Court affirmed the district court’s vacatur of the agency action and confirmed that vacatur is the appropriate default remedy. *Texas v. Biden*, 20 F.4th at 1000. And Fifth Circuit precedent says the APA “empowers and *commands* courts to set aside unlawful agency actions.” *Tex. Med. Ass’n*, 110 F.4th at 779 (emphasis added) (cleaned up).

Defendants next argue vacatur should be limited to the State of Texas. Dkt. 20 at 36. But as the Fifth Circuit has recently reaffirmed, “party-restricted vacatur” is an oxymoron. That is because by its nature, the “scope” of vacatur under § 706 is “‘nationwide . . . not party-restricted,’” “and ‘affects all persons in all judicial districts equally.’” *Braidwood Mgmt., Inc. v. Becerra*, 104 F.4th 930 (5th Cir. 2024) (quoting *In re Clarke*, 94 F.4th 502, 512 (5th Cir. 2024) and *Career Colleges & Sch. of Texas v. United States Dep’t of Educ.*, 98 F.4th 220, 225 (5th Cir. 2024))).

This reading accurately reflects the difference between the APA context—where vacatur of a rule “for everyone” is the normal remedy, *Kiakombua v. Wolf*, 498 F. Supp. 3d 1, 52 (D.D.C. 2020) (K.B. Jackson, J.) (citation omitted); *see also Career Colleges & Schools of Texas*, 98 F.4th at 255—and non-APA cases involving requests for equitable relief that flow to particular parties. *Cf. Griffin v. HM Florida-ORL, LLC*, 144 S. Ct. 1, n.1 (2023) (Kavanaugh, J., concurring in denial of stay) (explaining difference); *see also* Jonathan F. Mitchell, *The Writ-of-Erasure Fallacy*, 104 Va. L. Rev. 933, 950 (2018) (“[T]he [APA] establishes a unique form of judicial review that differs from judicial review of statutes.”).

Finally, Defendants urge this Court to salvage some of the 2024 Rule with severability. Dkt. 20 at 36. In support, Defendants make passing reference to a severability clause. *Id.* at 37. “But ‘the ultimate determination of severability will rarely turn on the presence or absence’ of a severability clause.” *Nasdaq Stock Mkt. LLC v. SEC*, 38 F.4th 1126, 1145 (D.C. Cir. 2022). Defendants offer “no guidance on how the Court should excise the offending provisions,” *Texas v. Becerra*, 739 F. Supp. 3d 522, 541 (E.D. Tex. 2024), even though that was their burden. *See, e.g., Texas v. EPA*, 829 F.3d 405, 435 (5th Cir. 2016).

Even were the Court inclined, the scant briefing on the issue puts it in the “ untenable position” of having to parse the [triple-columned, 91-] page Final Rule [itself] to determine the practicability and consequences of” more limited relief. *Murrill*, 2024 WL 342887, at *2. This is not the Court’s job, *see Murthy v. Missouri*, 603 U.S. 43, 67 n.7 (2024), and it should decline the offer.

There is “substantial doubt” that the agency would have adopted an emasculated form of the 2024 Rule, *Balt v Azar*, 439 F. Supp. 3d 591, 615 (D. Md.), *aff’d*, 973 F.3d 258 (4th Cir. 2020),

which, as a “comprehensive regulatory package[,] is plainly not amenable to severance.” *Chamber of Com. of U.S. v. Dep’t of Labor*, 885 F.3d 360, 388 (5th Cir. 2018), because its components are “intertwined,” “giv[ing] rise to a substantial doubt that a partial affirmance would comport with the [agency’s] intent.” *Telephone & Data Sys., Inc. v. FCC*, 19 F.3d 42, 50 (D.C. Cir. 1994). The chief purpose of the 2024 Rule is to counteract States’ restrictions on access to abortion. *See, e.g.*, 89 Fed. Reg. 32,987. Erasing major provisions fatally undermines the rationale for the rule. *See Baltimore*, 439 F. Supp. 3d at 615.

If Defendants’ provision curtailing the use and disclosure of “reproductive health care” information falls, then the 2024 Rule won’t “survive . . . in anything approaching recognizable form.” *North Carolina v. EPA*, 531 F.3d 896, 929 (D.C. Cir. 2008).

CONCLUSION

For the foregoing reasons, Texas respectfully requests that the Court grant summary judgment in its favor on all claims challenging the 2024 Rule and grant Texas all relief at law or equity to which it is justly entitled. A proposed form of order is attached.

Dated: June 9, 2025

Respectfully submitted.

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CERTIFICATE OF SERVICE

I certify that this document was filed via the Court's ECF system on June 9, 2025, providing service to all counsel of record.

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